K120241

FEB 2 4 2012

510(k) Summary

Date: February 24, 2012

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: teffany.hutto@djosurgical.com

Product	Classification	Product Code
Linear Porous Coated Hip Stem, Size 5	Class II	LPH, LZO

Product Code	Regulation and Classification Name
LPH	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis per 21 CFR 888.3358
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. per 21 CFR 888.3353

Description: The Linear Porous Coated Hip Stem is fabricated from wrought/forged Ti-6Al-4V. It is collarless and has a Morse type taper to receive modular heads. This stem is available with a standard offset and a lateralized offset version that provides additional lateralization of the patient's femur without increasing leg length. The stem/neck angle is 135°. This change will add an alternate porous coating.

Indications for Use:
The indications for use of the total hip replacement prosthesis include: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. This stem is to be press-fit.

Predicate Devices:

DJO Surgical Linear Hip Stem, Size 5 - K991325
DJO Surgical Porous Coated Hip Stems - K081679

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same design features, materials, indications sterilization, packaging and intended use.

Non-Clinical Testing: Fatigue testing of the size 5 stem demonstrated the device's ability to perform under expected conditions. Prior testing of the alternate porous coating in K081679 included shear strength, tensile strength, shear fatigue strength, and rotating beam fatigue.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2012

Encore Medical, L.P.
% Ms. Teffany Hutto
9800 Metric Boulevard
Austin, TX 78758

Re: K120241
Trade/Device Name: Linear® Porous Coated Hip Stem, Size 5
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO
Dated: January 27th, 2012
Received: January 27th, 2012

Dear Ms. Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K120241

Device Name: Linear Porous Coated Hip Stem – Size 5

Indications for Use:

Linear Porous Coated Hip Stem – Size 5
Indications for Use

The indications for use of the total hip replacement prosthesis include: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. This stem is to be press-fit.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

E. M. Keith

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120241